

Cervical Cancer Prevention Program in Coimbatore district of Tamil Nadu state, India

Master of Public Health Integrated Experience Project

Program Implementation Grant Proposal

By

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Abbreviations

ACS:	American Cancer Society
CIN:	Cervical Intraepithelial Neoplasia
CCAM:	Cervical Cancer Awareness Measurement
CEO:	Chief Executive Officer
CKC:	Cold Knife Conization
CHW:	Community Health Workers
DNA:	Deoxyribonucleic Acid
GDP:	Gross Domestic Product
HBM:	Health Belief Model
HPV:	Human Papilloma Virus
HC:	Hybrid Capture
IRB:	Institutional Review Board
IARC:	International Agency for Research on Cancer
LBC:	Liquid Based cervical Cytology
LCD:	Liquid-Crystal Display
LEEP:	Loop Electro Surgical Excision Procedure
MPH:	Master of Public Health (MPH)
Obs/Gyn:	Obstetrician/ Gynaecologist
NPCDCS:	National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke
PCR:	Polymerase Chain Reaction
SHG:	Self-Help Group
TOT:	Training of Trainers
UK:	United Kingdom
USD:	United States Dollar
VIA:	Visual inspection using Acetic Acid
VILI:	Visual inspection using Lugol's Iodine
VIAM:	Visual Inspection using Acetic Acid with low level magnification
WHO:	World Health Organization
YLS:	Year of life saved

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1. Executive Summary

Cervical cancer remains one of the major public health issues in India. Lack of knowledge about cervical cancer and its preventive measures, the absence of organized screening program, and poor access to diagnosis and treatment are identified as the potential barriers to reduce the burden of cervical cancer in India.

The aim of this proposed program is to reduce the burden of cervical cancer in Coimbatore district of Tamil Nadu state, India by implementing an evidence-based organized cervical cancer prevention program. The merit of this program is that it will use an advanced rapid HPV DNA test (*care HPV*) that will produce the result in 3 hours; hence the treatment can be given on the same day. This will greatly support the 'screen-and-treat approach' that is recommended by WHO recently. To achieve this goal, the program has three objectives; increase the women with satisfactory or good knowledge to 20%, promote the screening behavior of women to 30%, to show a 30% reduction in cervical cancer incidence rate.

The total duration of the program will be five years. The key players of the program are public health professionals, physicians, nurses, community health workers, members of women self-group. Formal educational sessions, scheduled screening campaigns, counseling, treatment on the same day, referral for diagnosis and treatment, follow-up of referrals are the major activities of the program. There will be one mid-term and one final evaluation to assess the impact of the program.

Thus by implementing evidence-based organized screening program in Coimbatore district, the burden of cervical cancer will be reduced significantly.

2. Situational analysis

2.1.Cervical cancer

According to American Cancer Society (ACS), '*cervical cancer starts in the cells lining the cervix the lower part of the uterus*'.¹ The cervix is the organ that connects uterus and vagina.¹ It is usually slow-growing cancer that can be found by regular cytological method of screening known as Pap test.¹

2.2.Global burden

Cervical cancer is the fourth common cancer among women and seventh overall with an estimated 528,000 new cases in 2012.² Developed nations showed more than 70% reduction in the incidence rate of cervical cancer in the past 50 years.³ Nevertheless, in developing nations, the issue seems to be on the rise.³ Developing nations have high age-specific incidence rate per 100,000; Eastern Africa (42.7), Melanesia (33.3), Southern (31.5) and Middle Africa (30.6).⁴ On the other hand, rates are lower in developed nations such as Australia/New Zealand (5.5) and Western Asia (4.4).⁴

2.3.Etiologic Factors

The major etiologic factor of cervical cancer is human papilloma virus (HPV).⁴ More than eighty different types of HPVs were identified, and approximately fifty percentage of those HPVs can affect human genital organs.^{5,6} Out of these, fifteen types (16,18,31,35,39,45,51,52,56, 58,59,68,73, and 82) are found to be high risk types; three other types (23,56, and 66) are considered probable high-risk types; twelve types (6,11,40,42,43,44,54,61,70,72,81, and CP6108) as low risk; three types (34,57, and 83) as undetermined risk groups.⁷ HPV types 16

and 18 are the most common causes of cervical cancer in all countries with the overall prevalence of 59%, and 15%, respectively.⁷

2.4.Risk factors

- There is a significant association between long-term use of oral contraceptives and cervical cancer.^{8,9,10}
- High parity has a positive association with cervical cancer due to the presence of transformation zone on the ectocervix for a longer duration. These women are highly susceptible to the HPV infection thus develop pre-cancerous lesions.^{9,11}
- Age (early) at the first intercourse, characteristics (e.g. smoking) of the selected sexual partner, and biological factors such as cervical immaturity are associated with HPV infection and its persistence.¹²
- Smoking (active and passive) plays a vital role in changing the persistent infection or pre-invasive lesions to an invasive lesion and eventually cervical cancer.^{9,13,14}
- There is an association between lack of awareness due less education and occurrence of cervical cancer which is continued to be a major public health issue in many developing countries including India.^{15,16}

2.5.Pathogenesis of cervical cancer

The female reproductive system is divided into external and internal organs. External genitalia comprised of major and minor labia, clitoris, urethra, and vaginal opening.¹ The internal genitalia consists of vagina, cervix, uterus, fallopian tubes and ovaries.¹

The normal cervix is covered with non-keratinized squamous epithelium that is continuous below with the squamous epithelium lining the vaginal canal and above with the mucous secreting columnar epithelium lining the endocervical canal.¹⁷ Physiologically, in puberty, delivery, and during oral contraceptive use the above mentioned squamocolumnar junction comes out to the ectocervix and forms a tissue layer known as cervical ectopy.¹⁷ This cervical ectopy becomes more vulnerable to cervical intraepithelial neoplasm (CIN) and invasive carcinomas.¹⁷

Cervical intraepithelial neoplasm (CIN) otherwise known as premalignant lesion is divided into three categories; CIN1, CIN2, and CIN3.^{17,18} The well differentiated intraepithelial neoplasm is known as CIN I, the less differentiated as CIN 3, and the intermediate level is known as CIN 2.¹⁷ Diagnosis of CINs are made Based on the location of cytoplasmic maturation.¹⁷ For example, in CIN1 lesions the maturation occur at the superficial 2/3 of epithelium, in CIN2 the maturation happens at the middle third, and in CIN3 lesions the maturation changes occur at the more superficial or even absent.¹⁷

Over 50% of the CIN1 relapses to normal even without treatment whereas the high-grade lesions of CIN2 and CIN3 (also known as CIN2+) progress to invasive carcinomas.^{17,18} Invasive cancer usually lie over the ectocervix in young females and in endocervix in elder women that make the diagnosis difficult among older women.¹⁷ The cervical carcinoma can spread (metastasis) to the vicinity organs such as vagina, body of uterus, cervical stroma, and during the late course even to the rectum and urinary bladder.¹⁷

2.6. Prevention of cervical cancer

According to World Health Organization (WHO), the aims of the preventive and control program are to reduce the incidence, morbidity, and mortality rates of cervical cancer.²⁰ There are three steps to accomplish these aims; (i) Primary prevention; (ii) Secondary prevention; (iii) Tertiary prevention.¹⁸

2.7.Primary prevention

The aim of the primary prevention is to restrict the pathogenic process of cervical cancer before it starts.¹⁹ This can be achieved by either total abstinence from unprotected sexual activity or by vaccination.¹⁹ Following are the guidelines of WHO for the primary prevention of cervical cancer;¹⁸

- HPV vaccination to girls aged from 9 to 13 years.
- Education to all boys and girls about tobacco use and its ill effects
- Sexual education to both genders based on age and culture
- Promotion and provision of condom for people engaged in sexual activity
- Male circumcision (surgical removal of skin covering the penis)

2.8.Secondary prevention

The aim of secondary prevention is to prevent the progression of the pathogenic process into disease when already the exposure took place.¹⁹ According to the International Agency for Research on Cancer (IARC), the following screening tests are available.²⁰

i. Cytological methods

- Cervical cytology (Pap smear)
- Liquid-based cervical cytology (LBC)

ii. Visual inspection methods

- Visual inspection using Acetic Acid (VIA)
- Visual inspection using Lugol's Iodine (VILI)
- Visual Inspection using Acetic Acid with low-level magnification (VIAM)

iii. HPV DNA testing methods

- Hybrid Capture assay (HC)
- Polymerase Chain Reaction (PCR)
- *Care* HPV test

2.9.Tertiary prevention ²¹

- Treatment of invasive cancer at any age
- Surgery
- Chemotherapy
- Radiotherapy
- Palliative care

3. Strategy appraisal

The proposed program will focus on the secondary prevention of cervical cancer. It will use an advanced rapid HPV DNA test as a screening tool and Cryotherapy as a treatment modality. In the following paragraphs, comparative analysis of screening tests and treatment methods and evidence for choosing these two methods as the option of secondary prevention are provided.

3.1. Screening methods

A good screening method must have accuracy, reproducibility, less expensive, easy to perform, easy to follow-up, acceptable and safe.^{20,22} Conventional cytology (Pap smear), HPV DNA test and visual inspection methods (VIA and VILI) are considered to satisfy the above-mentioned criteria²² and described below.

Screening method	Description	Sensitivity/specificity	Advantage	Disadvantage
Pap smear test	A sample of cervical cell is taken by the provider, fixed into the slides and examined by the cyto- technician in the lab	Sensitivity: 62% Specificity: 90%	High specificity Effective in context of well-functioning system Well accepted in high-resource settings	Lower sensitivity Difficulty to establish in resource poor setting Need for transportation of specimens to laboratory and back to clinic Interpretation is subjective Results are not available immediately Loss to follow-up Quality control and quality assurance
VIA	A trained provider examines cervix after application of 3-5% acetic acid.	Sensitivity: 73.2% Specificity: 86.7%	Any trained provider can perform Relatively simple and less expensive	Need for continuous training of providers Poor quality control and assurance

Screening method	Description	Sensitivity/specificity	Advantage	Disadvantage
			Minimal the requirement of infrastructure Results available immediately	Accuracy is uncertain due to subjective interpretation of results Not appropriate for post-menopausal women
HPV DNA test	Sample is taken by the provider or women Stored in container with preservative Transported to the lab for the process of DNA assay	Sensitivity: 95% Specificity: 95%	Simple specimen collection (self) Assay result is the definite end point Objective interpretation of results	Need of well-equipped laboratory High unit cost and Poor access Challenges in storage, transportation Results not available immediately Need of multiple visits and Loss to follow-up Need of quality control and assurance
Rapid HPV DNA test (<i>care</i> HPV Test)	Sample is taken by the provider or by the women Process of assay is done on the screening site Result will be obtained in 2-3 hours	Sensitivity: 90% Specificity: 81.4%	Good sensitivity Self-collection of sample and less unit cost Short time for process and result: 2.5 hours	Comparatively low Specificity: Self-collection would not be as accurate as provider collection

Screening method	Description	Sensitivity/specificity	Advantage	Disadvantage
			<p>Immediate result: Treatment on same day minimize loss to follow-up;</p> <p>Objective, good quality control and assurance</p> <p>No need for laboratory</p>	

3.1.1. Pap smear (Pap) test

It comprises the collection of cervical tissues (sample is taken out from the transformation zone of the cervix with the help of a wooden spatula), preparation of slides, staining, reading the results and reporting to women.²² Hence, there are a need for well -trained cytotechnicians as well as highly equipped laboratories, good quality control system.¹⁹ Though Pap smear is considered as one of the mainstays of cervical cancer prevention until now, the accuracy of this method has been questioned in recent years.^{19,20} Even if all the requirements mentioned above are fulfilled, it has less sensitivity (62%) in identifying CIN2 and CIN3 lesions and the specificity is 90%.¹⁹

Inadequate financial resources, lack of trained staff, poor infrastructure, poor access, and ineffective referral mechanisms hindered the organization of effective cytological screening

programs in low or middle-resource countries.¹⁹ This eventually leads to the invention of alternative methods of screening methods that are tailor made for developing countries.¹⁹⁻²³

3.1.2. Visual Inspection methods

i. Visual inspection of cervix using Acetic Acid (VIA)

VIA is performed by naked-eye inspection of the cervix, one minute after the application of a 3–5% solution of acetic acid using a cotton swab or a spray.^{19,20} Test positivity is based on the appearance of acetone white areas in the transformation zone, close to the squamous-columnar junction of the cervix.^{19,20} A cluster randomized trail conducted in one of the districts of Tamil Nadu (Dindigul) from 2000-2003 to assess the effect of VIA in reducing incidence and mortality rate of cervical cancer.²⁴ The study results found that there was a 25% reduction in the incidence rate and 35% reduction in the mortality rate among intervention group when compared to the control group.²⁴ Even though, VIA was an effective method of screening in low-resource settings, high-quality training for providers, continuous quality control, and monitoring would be crucial in achieving a successful VIA screening campaigns.²⁴

ii. Visual inspection of cervix using Lugol's Iodine (VILI)

In this method, the cervix is visualized after the application of Lugol's iodine that reacts with the glycogen in the cervical cells and produces different colors.^{19,20} The positive result is based on the appearance of bright mustard or saffron yellow color on the squamous epithelial junction of the cervix that contains little or no glycogen.^{19,20}

Evidence suggest that the sensitivity and specificity of VIA ranged are 73% and 87% respectively. Likewise, sensitivity and specificity of VILI are 88% and 86% respectively.^{23,25,26,27}

These tests have many advantages; simplicity, less expensive, do not require a sophisticated laboratory, less training period to providers (5–10 days) as compared to the training of cytotechnicians (12–24 months), immediate availability of the test result makes it tailor made for low resource settings.^{23,25,26,27} On the other hand, the specificity of these visual inspection methods are comparatively low than the conventional cytological tests. Hence the diagnostic confirmation again depends on laboratory.²⁷ Quality control, close monitoring of positivity and requirement of periodic training to the health workers are the challenging aspects of these methods.^{24,27}

3.1.3. HPV DNA test

In these tests, samples are collected from cervix and vagina and are examined in a well-established laboratory for high-risk HPV DNA.¹⁸ Hybrid capture assay (HC) and polymerase chain reaction (PCR) are widely used methods for HPV DNA testing.²⁰ Totally, thirteen types (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68) of HPV can be identified by this method.²⁰ The sensitivity of HPV DNA testing is proved as 95%, and the specificity is 95%.^{18,20,28,29,30,31} High cost, need of high standard laboratory and well-trained technicians, challenges in transporting the specimens and quality control make this method as not feasible in resource-poor settings.^{18,20}

A cluster randomized trial conducted in the Osmanabad district of Maharashtra state of India with the aim to assess the effectiveness of HPV testing to reduce cervical cancer incidence and mortality in comparison with Pap smear and VIA.³² It was found that the cumulative incidence rate of stage II or higher cervical cancer was 1/1000 among the HPV testing group and 3/1000 in control group.³² The cumulative incidence rate was higher among VIA (2.5/1000)

and Cytological (2/1000) group.³⁴ This study recommends that HPV DNA test is effective in reducing the incidence and mortality rate of cervical cancer in India when compared to other tests.³⁴ However, the unit cost (\$20-\$30), delay in obtaining the results, the need for sophisticated laboratory make this test an unaffordable in resource-poor settings.³⁴

3.1.4. *care* HPV Test

To address the disadvantages mentioned in the cytological method,¹⁹ visual inspection²⁴ as well as in HPV DNA testing methods,^{18,20} an advanced rapid HPV DNA testing method named as *care* HPV test was invented by the collaborative research of PATH (funded by Bill and Malinda Gate's foundation) and QIAGEN corporation.³³ This new HPV-DNA test is based on hybrid capture technique that detects 14 different types of carcinogenic HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).³³

A cross-sectional study published in Lancet Oncology showed that the sensitivity and specificity of *care* HPV test were 90% and 84% respectively.³⁵ By *care* HPV test the result can be obtained in 2-3 hours. Thus, the treatment can be started on the same day.³⁵ This will greatly reduce the loss to follow-up.³⁵ Self-collection of samples is an attractive option in *care* HPV test among women that will significantly reduce one of the major barriers (embarrassment), especially in developing nations.³⁵ A cross-sectional study conducted in India showed that the self-collection of the sample in *care* HPV will increase the screening performance, and adoption of this rapid HPV DNA test will greatly reduce the cost of the screening program.³⁴ Another multi-country evaluation of *care* HPV test with visual inspection and Pap smear test showed that adoption of *care* HPV test will significantly increase the screening coverage and early detection of cervical cancer in low-resource settings.³⁵

3.2. Cost-effectiveness analysis

A cost-effective analysis of various screening methods (Pap smear, visual inspection, and HPV DNA test) in India proved that one visit HPV DNA test per lifetime is associated with 32% reduction of cervical cancer, which is equivalent to two visits per lifetime (HPV plus VIA) screening test and three visits for Pap smear test.²³ If HPV DNA test was done twice per lifetime, then there will be a 55% reduction in the risk of cervical cancer.²³ This is equivalent to three times, two-visit approach (using HPV DNA test and VIA).²³ Also, three visits HPV DNA test is associated with 60% reduction in cervical cancer in India, which is superior to all the screening methods.²³ The one-time ‘*screen and treat*’ approach with HPV DNA test is associated with 152 US\$ year of life saved (YLS), two-time HPV DNA test is associated with 268 US\$ YLS, and three-time HPV DNA test is associated with 591 US\$ YLS in India.²³ The total lifetime cost will be 25 international dollars (one time HPV DNA test per lifetime) to 35 (three times per lifetime HPV DNA test). Hence, the proposed program will one-time screen and treat approach using *care* HPV test as the primary screening method.

3.3. Sensitivity analysis

Sensitivity analysis is a term used to describe a series of methods for isolating factors in decision-making investigation and determine the influence of each factor on the result of investigation.³⁶ In this analysis, base-case estimates are used; base case estimates the best available data or the investigators best guess at the true value for a factor.³⁶ The aim of sensitivity analysis is to examine the consequences if the base case estimate does not turn out to be accurate.³⁶ Thus we can set a realistic high value and a realistic low value that provides a range of values.³⁶ This can be viewed like a 95% confidence interval; the interval here is termed as credibility interval.³⁶

A sensitivity analysis conducted for *care* HPV test showed that when the cost associated with invasive cancer were doubled, the cost effectiveness associated with *care* HPV test increased to US\$ 90 YLS for one visit, US\$ 120 YLS for two visits, and US\$ 200 YLS for three visits per lifetime screening.³⁷ Also, doubling the cost of treatment of precancerous lesion using *care* HPV is associated with the high impact of cost-effectiveness ratio; US\$ 130 YLS for one visit, US\$ 160 YLS for two visits, and US\$ 250 YLS for three visits per lifetime.³⁸ Thus, *care* HPV can be considered as very cost effective.³⁹ As the sensitivity of *care* HPV test varied from 60 to 95% (keeping base case at 83.5%), the cost-effectiveness varied by less than 10% GDP.³⁹ On the other hand, the specificity of *care* HPV test varied from 60 to 99% (keeping base case at 87.5%), the cost-effectiveness ratio varied from US\$ 190 to US\$ 130 per YLS which is a fraction of per capita GDP.³⁹

The cost-effectiveness of screening methods is sensitive to the cost associated with the treatment of invasive cancer.²³ If the cost associated with invasive cancer doubled, the cost effectiveness of single time screening with HPV DNA test is less than 500 US\$ per year of life saved.²³ In India, if the cost of HPV DNA test is reduced by 50%, two visit HPV-DNA testing dominated one visit visual inspection testing and cost US\$ 1 per life of years saved for one screening, 73 US\$ for two screening, and 231 US\$ for three screening in a lifetime.²³

If the screening coverage reduced to 50%, there will be the same proportional increase in expected incidence of cervical cancer and vice versa.²⁵ The screening program results are also sensitive to loss to follow-up.²⁵ For example; a 5% reduction on loss to follow-up in two visits approach will be more attractive.²⁵ Thus, the screening program focusing on one visit or two visits HPV DNA test or visual inspection test will reduce the lifetime risk of cervical cancer from 20-35%.

Therefore, higher sensitivity, affordability, low processing time (2-3 hours), accuracy, self-collection of samples, easy to follow-up, treatment on the same day, and good quality control make the *care* HPV test a feasible one to reduce cervical cancer incidence and mortality in low-resource settings.^{26,32,33, 34,37, 39, 41}

3.4.Treatment options as secondary prevention²⁰

Women who identified as positive in screening test should receive treatment to prevent the progression of pre-cervical cancer to invasive cancer. It is the role of health care providers to counsel the women about the treatment options and let her take decision. There are three treatment methods commonly used; cryotherapy, loop electrosurgical excision (LEEP), and cold knife conization (CKC).

3.4.1. Cryotherapy¹⁸

Cryotherapy eliminates the precancerous areas of the cervix by freezing. In this modality, a highly cooled metallic disc is inserted into the cervix that freezes the abnormal areas. Cryotherapy can be performed by all levels of health care providers (doctors, nurses, and midwives). It takes 15 minutes to complete and usually well tolerated by the women with only mild discomfort. After the procedure, it takes one month for the regeneration of cervical tissue. The woman should be informed that she will have profuse watery discharge, and she should avoid sexual intercourse until the discharge stops otherwise use a condom in case if the sexual intercourse is unavoidable.

3.4.2. Loop electrosurgical excision procedure (LEEP)¹⁸

LEEP is the removal of abnormal areas from the cervix using a thin wire that is powered by an electrosurgical unit. The removed tissue can be sent for histopathological examination. Thus it also helps to take tissue for diagnosis. It is performed under general anesthesia, takes 30

minutes to complete, and needs a minor surgical room. The patient has to wait for few hours in the facility to monitor for any post-treatment complication. Hence, this method would not be an appropriate one for the proposed program. However, the physician (team leader) will refer the woman who will be identified as positive and in need of LEEP to the hospital.

3.4.3. Cold knife conization (CKC)²⁰

CKC is the removal of a cone-shaped lesioned area from the cervix. This also provides tissue for laboratory examination. The health care providers who have surgical skills (gynecologist or surgeon) do this procedure in the hospitals. It is performed under general or regional anesthesia. Since the method depends on the surgical unit and surgeon, this also is not the appropriate one in this proposed program. Nonetheless, the physician (team leader) will refer the woman who will be identified as positive and in need of CKC to the hospital. Among all, cryotherapy is chosen as the treatment option for the proposed program as it has many advantages over other methods.

3.5. Barriers to achieving effective secondary prevention

There are numerous factors that are potential barriers to achieving the effective screening programs all over the world.³⁸ These are lack of knowledge, the screening procedure itself, location of the clinics (less access), emotional barriers such as embarrassment, fear of pain, fear of diagnosis with cancer, inconvenience, and cognitive barriers such as lack of perceived severity, susceptibility are key factors.^{38,39} Hence, cervical cancer prevention program should be designed to address the above-mentioned obstacles.^{37,38}

3.6.Situation in India

In India, the population of women aged over 15 years is 432 million who are at risk of developing cervical cancer.¹⁵ Each year 122,844 women are diagnosed with cervical cancer and 67,477 die due to the disease.¹⁵ Among other Asian countries, India has the highest age-adjusted incidence rate (22/100000).¹⁵ From 2009 to 2011, Aizawl district of Mizoram state in India (Northern East) had the highest cervical cancer levels with an age-adjusted rate of 24.3% whereas, Dibruhargh district of Assam state recorded lowest levels of incidence rate (5.6%).^{15,40}

India has had a national program for cancer since 1995 that has been evolved over time.¹⁶ In 2010, Government of India established National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS).⁴¹ This is a pilot project targeted 100 backward districts from 21 states across India.⁴⁰ Early diagnosis of above mentioned non-communicable diseases through screening, referral, and treatment of those diseases are the key strategies of this program.⁴⁰ Nonetheless, there were no organized cervical cancer screening campaigns in India at present.¹⁶ As a result, screening coverage is very low in India; it ranges from 7% in Kerala (neighbour state of Tamil Nadu) to 0.002% in Tamil Nadu.¹⁶ This coverage is happening commonly by opportunistic screening (women are screened for cervical cancer when going for other gynecological related problem) and not by organized screening campaigns.¹⁶

According to the literature, several factors associated with the utilization of cervical cancer screening tests. These factors related to knowledge, socio-economic status and demographic status (education, income, religion, transport) of women, resource and psychosocial factors (lack of interest, and fear of screening procedures).^{45, 46, 47, 48} In India, the knowledge

level of cervical cancer is poor. Evidence shows that only 6% of women have good knowledge about cervical cancer, and only 1.2% of women have good knowledge about screening tests.⁴²

3.7.Tamil Nadu

Tamil Nadu is one of the southern states of India and Chennai (formerly known as Madras) is the capital city.⁴³ According to 2011 census, the total population of Tamil Nadu was 72,147,030 in which women approximately 50% were women.⁴⁴ In 2011, total literacy rate in the state was 80% (male: 86.7% and female: 73.4%).⁴⁴

3.7.1. Burden of cervical cancer in Tamil Nadu

In 2009, the age-adjusted incidence rate of cervical cancer among women in Tamil Nadu was 17 per 100000, which was two folds higher than in the neighbour state of Kerala (8%).¹⁵ Even though the predicted value of cervical cancer burden seems to decrease in Chennai, it remains same in the Tamil Nadu state.⁴⁵ The prevalence of HPV infection ranged from 17% to 74% in the rural districts of Tamil Nadu.⁴⁶ Higher prevalence of HPV infection was found among women who are less educated as well as working outside the home (e.g. farmers).⁴⁶ In addition to HPV infection, poverty, high parity, less education, sexual behaviour of women's husband (extramarital sexual relationship), early menopause, are identifies as risk factors for cervical cancer in Tamil Nadu.⁴⁷ Therefore, promoting awareness and perceived severity among women in India will increase the uptake of screening and eventually reduces the morbidity and mortality rate of cervical cancer.^{45, 46, 47, 48}

3.8. Overview of Coimbatore district

Coimbatore is the third largest and most industrialized district in Tamil Nadu. Coimbatore is also known as the textile capital of South India.⁴⁸ According to the official census of 2011, Coimbatore district had a population of 3472578 of which approximately 50% (1737216) were women. The total literacy rate was 76 % in 2011.⁴⁹ Totally there are 10 Talukas (administrative capitals of villages) and 295 villages.⁴⁸

3.9. Outline of the proposed program

Taking into consideration the burden of the issue in India, the proposed program provides an evidence-based approach to reducing the burden of cervical cancer in one of the districts (Coimbatore) of Tamil Nadu state, India. The program has three phases; planning; implementation; and evaluation. In the planning phase, recruitment of human resource, training of trainers, purchase, allocation of resources, demonstration project are the key tasks. In the implantation phase, promotion of knowledge and screening behaviour of women through the educational campaign, conducting screening campaigns using rapid HPV DNA test (*care* HPV test) as the primary screening method and treatment by cryotherapy are the key tasks. There will be two evaluations in the program; one mid-term and one final evaluation will be conducted.

3.10. Target population

As it is mentioned earlier, the female population of Coimbatore district was 1.7 million according to 2011 census.⁴⁹ The proposed program assumes that 50% (868608) of this female population will be between the age group of 30-59 years. It also assumes that 50% of women in

this age group will be eligible for this program. Therefore, the total number of women who will benefit from this program will be approximately 400,000.

4. Allocation of resources

The proposed program will cover 295 villages of Coimbatore district in five years. At first, recruitment of human resource will be completed in the planning phase. This proposed program will involve various levels of health care workers (public health professionals, physicians, nurses, medical social workers). They should have the skills in communicating with the local people in their language (Tamil).

The next task of the program will be finding/establishing the local office premises. Since the program covers 10 Talukas, there will be ten regional offices/centers. The team leader who will be a physician will be the head of each regional office and supervise field leaders and field staff. All the supplies such as screening kit, treatment kit, information and technology services, educational materials, office utilities, and transport services will be purchased and distributed based on the request by the team leaders. To do this, team leaders, and field leaders will conduct a need assessment during the planning phase of the program. It is the responsibility of team leaders and field leaders to use the supplies appropriately according to the local need.

The next task of the program will be the allocation of financial resources. The program will have one senior accountant and two junior accountants. The senior accountant will work in coordination with the chief executive officer (CEO) of the program. Based on the need assessment, the CEO will control the flow of funding. The program will fund the regional offices

on a monthly basis. This will include the salary, rental, electricity charge, transport allowance, and funding for other services such as the internet, telephone, and maintenance.

Purchasing of the medical supplies will be the crucial task before the implementation phase. The *care* HPV™ kit will be purchased from QIAGEN® which is the manufacturer of the kit. Their regional office for India is located in Mumbai city. So the program leaders will establish the official collaboration with them to import the kit for the program. After purchasing the item, the program leaders will invite the trainers from QIAGEN® to train the program staff to do the process. After finishing the training, the screening kit will be distributed to regional offices.

Purchasing of cryotherapy unit is the next task. According to WHO technical specification that is designed for cryo surgical unit and its local manufacturer, Appasamy Associations is one of the authorized manufacturers in India.⁵⁰ The program will establish collaboration with them and purchase the treatment unit as per the needs. After purchasing, the manufacturer will give training to the program staff (e.g. nurse) on how to do the procedure.

The educational materials (for trainers and target women) will either be collected online or purchased from the authors. For example, some of the educational materials made by **Grounds for Health** organization, available online and can be used for the educational purpose of the program.⁵¹ Other supplies for the educational program such as *liquid-crystal display projector* (LCD) will be purchased locally and distributed to the regional offices.

5. Programming

5.1.Goal

To reduce the burden of cervical cancer by '*screen and treat*' approach among women of Coimbatore district, Tamil Nadu state, India.

5.1.Objectives

1. The proportion of women (30-59 years old) with satisfactory or good knowledge about cervical cancer and its screening will increase to 20%, four months after the educational intervention in Coimbatore district.
2. By implementing an educational program that is based on Health Belief Model, the health seeking behavior (willingness to screen) of women (30-59 years old) will increase to 30% in Coimbatore district by five years.
3. By using *care* HPV test in '*screen and treat approach*'; there will be a 30% reduction in cervical cancer incidence rate among women (30-59 years old) of Coimbatore district by five years.

As it is already mentioned, to achieve the goal and objective, the proposed program will be divided into three stages program planning, program implementation, and evaluation. There will be two phases of planning, two phases of implementation, and two evaluations. The proposed program will use WHO' comprehensive cervical cancer control guidelines (second edition).¹⁸

5.2.Program planning

This will be the first step of the whole program. The proposed program will use the first three months to plan the first phase of implementation of the program. Recruitment of human resource, establishing infrastructure at the village administrative blocks (also known as Talukas),

training of trainers, purchasing the supplies, allocating them to the regional offices are the initial activities of this phase.

After recruiting them, training of trainers (TOT) will be provided to all levels of workers. By the end of TOT, all staff will have the skills on educating local women about cervical cancer and its ill effect, screening methods and its benefits, treatments. Once they completed the TOT, each staff members will be assigned their duties and responsibilities based on the needs. They will have to work in their allotted areas in close coordination with superior officials.

5.2.1. Strategic approach to launch the program²⁰

There are four main steps that will be completed during the program planning phase

i. Determination of the target population

The proposed program will target women aged between 30-59 years old living in Coimbatore district of Tamil Nadu state. By setting the target population, the program team can assess the needed supplies, human resource, time, budget, and other resources

ii. Conduct need assessment

This involves visiting, observing, interviewing key informants and stakeholders such as representatives from women self-help group (SHG). Physicians, nurses, and community health workers will be involved in this phase. The aim of this phase is to assess the following

- Location, infrastructure of all health care facilities in the selected areas for the diagnostics and treatment purpose
- The existence and function of referral system in these facilities

iii. Map and acquire support from other local contributors

Since cervical cancer prevention program needs the involvement of various stakeholders, it is mandatory to pull the local organizations that are experts in the field of community services. At present in Coimbatore district, there are five cancer care centers including one government hospital. The program will establish an effective referral system with all the existing health care centers to achieve the proposed goal.

The proposed program will involve women self-group to conduct the educational and screening campaigns in the villages. Women self-help group (SHG) is a group of women usually 10-20 in numbers from similar class and region, who come together to form savings and credit organization.⁵² In 2014, the number of the self-help group in the district were 15651 that covered 21674 women.⁵³ In this program, a group of women from all SHG (from each Talukas) will be recruited for assisting the program team in delivering the education to the target women as well as to assist the screening campaign in their villages.

iv. Demonstration project before the start of the program

According to WHO guidelines, regions with limited resources can initiate a demonstration project in few selected areas before launching the program. For this purpose, one village in Coimbatore will be randomly selected, and the demonstration project (pilot project) will be conducted. Educational session, home visits, screening campaign, treatment, referral for diagnosis and treatment will be conducted in the village. This will give the basic idea of practical considerations before scaling up the whole program.

6. Budgeting

The proposed program seeks 698,700 US\$ for the human resource, infrastructure, and technical items (computers, travel expense). Evidence suggest that the cost of *care* HPV test per assay is approximately 5 US\$ and the program seeks 2,000,000 US\$ for screening alone. If we assume that about 50% of women will be given VIA to determine the eligibility for cryotherapy, then the program needs 1000000 US\$ for VIA service. If we assume that approximately 50 % of women eligible for cryotherapy (45 US\$ per treatment), the program need 4500000 US\$ for cryotherapy procedure. Hence the total budget for the program will be approximately 8198700 US\$. (See **Table 1: Budget of the program**)

7. Program implementation

7.1.The project team

The proposed program will have one chief executive officer (CEO), who will have Master of Public Health (MPH) degree with five years of experience. There will be four project leaders; two with MPH (2 years' experience) and two with gynecological oncology degree (2 years' experience). There will be ten team leaders; all are physicians with Obs/Gyn degree and two years' clinical experience. Ten field leaders will be recruited; all will be nurses with five years' experience. The proposed program will have thirty field staff (Community health workers, nursing midwife, a medical social worker) and 90 members (women) from women SHG. Each one has their duties and responsibilities. (See **Table 2: Project team and their duties and responsibilities**)(See **Appendix 1: Organizational Chart**)

The proposed program will be implemented in two phases; the first phase will cover the 50% of villages and the second phase will cover the remaining 50% of villages. Outreach, community mobilization, preventive health education, counseling will be provided to promote the screening coverage and adherence to treatment. Key players at this level are team leaders (physicians), field leaders (nurses), community health workers. The providers will be given the training to develop the following skills to have an effective interpersonal communication. By the end of the training session, all the providers will have the following skills

- Thorough understanding of cervical cancer and its preventive measures
- Capability to explain the topic to the audience in their local language
- Skills to alleviate social stigma by their communication; supportive; encouraging

7.2.Outreach

According to WHO, '*outreach refers to the efforts made beyond the walls of health care facility to reach target populations with the goals of increasing knowledge about cervical cancer prevention and increasing access to the services*'.¹⁸ For this program, the outreach will target women SHG, adult women aged from 30-59, and men.

Enough evidence has been given for selecting women aged from 30-59 years. Community leaders such as women self-help groups play a significant role to facilitate outreach programs in India. For example, presence of women SHG in the villages is associated with 48% higher odds of knowledge about family planning aiming rural women in Inida.⁵⁴ A pilot research program conducted in Tamil Nadu proved that first step towards gaining acceptance and support in community-based cervical cancer preventive program is educating women self-help group and

local male leaders to make them as local educators.⁵⁵ Creating community awareness regarding the benefits of early screening, gaining the trust of the local women, educating the community about the disease, and offering to screen, particularly in the rural areas, will more likely help in establishing a successful screening program.⁵⁵ Pamphlets; posters; radio; and local television channels will be utilized to reach all segments of the target population in a short period.

Since men are often the gatekeepers for their wives to obtain services in developing nations, their support is vital.²⁰ Providing information and education about HPV infection and cervical cancer to men in the target area at the community level will positively influence the participation of their wives. The proposed program will provide information to men in the villages by the field staff and women self-help group members. Men will be invited to attend the small educational sessions in their villages that will be organized by the field staff. In that session, key messages will be shared with men about cervical cancer, the importance of screening tests, and the role of men in encouraging women to attend the screening campaign. (**See Appendix 2: Key messages for men**).

7.3. Community mobilization

According to WHO, '*community mobilization is a process of engaging communities and generating support for all those in need of cervical cancer and control services, resulting in sustainable community ownership and participation*'.¹⁸

7.3.1. Engaging the community for prevention

Community leaders such as village administrators, teachers, and local politicians will be mobilized to identify the target population and make the people access the services. Community

health workers such as nurses, medical social workers, members of women SHGs and men volunteers will be mobilized to provide education.

7.3.2. Preventive health education

According to WHO, *'health education is an exchange of information with the purpose of increasing awareness and knowledge about how to keep healthy and prevent cervical cancer, including resources that are available and the benefit of accessing services'*.¹⁸ The aim of the preventive education is to address the barriers such as lack of knowledge about cervical cancer and its screening services. The objectives of the health education include:

- Increase the knowledge of signs and symptoms of cervical cancer and encourage them to seek care if they have them
- Promoting screening coverage among women of age between 30 and 59
- Assure treatment for women who are tested positive by effective referral system
- Addressing fear, embarrassment and stigma that are related to cervical cancer (**See Appendix 3: Essential knowledge about cervical cancer**)

7.3.3. Resources for educational campaigns

To increase the knowledge about cervical cancer, the proposed program will provide educational sessions that are based on WHO guidelines (**See Appendix 3: Essential knowledge about cervical cancer**). Thus, the first objective of the program will be achieved. To promote attitude and practice of screening, the program will use health belief model. HBM states that behaviour depends on two variables: (1) the value placed by an individual on an outcome and (2)

the individual's estimate of the likelihood that a given action will result in that outcome.⁵⁶ The HBM has six constructs; (i) perceived susceptibility (ii) perceived severity (iii) perceived barrier (iv) perceived benefits (v) cues to action (vi) self-efficacy (**See Table 3: the details of each construct**). Evidence show that HBM provides a theoretical guidance for the development of educational intervention and implementation.⁵⁷ Also, it has been proved that educational intervention based on HMB played a vital role in reducing the barriers and promoting the health seeking behaviour of women to practice cervical cancer screening.⁵⁸ Thus the second objective of the program will be achieved.

Training of trainers will be conducted at the regional program offices (administrative block of villages). Before the start of the educational sessions to providers, baseline data will be obtained by using a validated instrument (Cervical Cancer Awareness Measurement (CAM), UK) to assess the effectiveness of the session. The educational session will consist of lectures, video demonstration, pictures, small group discussions, question, and answer session. These methods are proved to be effective to achieve the stated objective of the program.⁵⁸ The total duration of the educational session will be two hours and immediately after the educational program; post-test will be conducted among the providers to assess their knowledge using the same questionnaire. After the session, community health workers will be guiding the women self-help group to proceed further with the outreach at the village level.

- According to WHO, for group education usage **flipcharts** will be effective that will have pictures which are easily understandable (complicated pictures like anatomy and virus will not be included)

- **Brochures** that contains information about cervical cancer and screening methods will be distributed; this can be taken home, and women can discuss them with their family members
- To convey short messages and announcements, **Mass media** (radio and television) will be used because it reaches a vast majority of target population shortly; visuals in television will attract target population very easily.

7.3.4. Delivering health education

- Based on the suggestions from local women, formal education sessions will be organized by community health workers and SHG to educate people about cervical cancer prevention and control
- Essential information about cervical cancer and the preventive measures will be taught to the target age group women guidelines. (See **Appendix 3: Essential knowledge about cervical cancer**).
- **Home visits** by community health workers and SHG will be undertaken. This is an effective method of addressing concerns about cervical cancer prevention and control; if possible, all family members will be made to involve in the discussion. Through this, the providers can reach the women who are not able to participate in the educational session.

7.3.5. Counseling for screening

Counseling refers to one-on-one advise or guidance from a knowledgeable person to facilitate personal decision making.¹⁸ Providers involved in this program at all level will be trained to conduct counseling. (See **Appendix 4: Guidelines for Counseling**).

7.4. Screen-and-treat approaches for pre-cancerous cervical lesion

The screen-and-treat approach is based on the screening that provides an immediate result and helps to treat the woman on the same day (if the woman shows willingness).²⁰ This approach has an advantage over the screen, diagnose, and treat approach. In the later method, treatment is given only after the confirmation by biopsy or colposcopy. Hence, the woman has to make an additional visit to the facility that leads to loss to follow-up.^{18,21} On the other hand, the former method needs only screening test result and the treatment will be performed if the test result is positive.¹⁸ Especially, in *care* HPV test; the result will be received within 3 hours thus the treatment will be given on the same day (if the woman agrees). This will greatly reduce the loss to follow-up and increase the treatment coverage. Lack of diagnostic test is considered as a limitation of this approach that will seldom result in false positive and overtreatment.¹⁸ Nonetheless; this can be weighed against the benefits by screen-and-treat approach; reduced morbidity due to application cryotherapy.¹⁸

7.5.Role of health care providers

The health care provider in this proposed program will ensure that women are educated about cervical cancer; that quality services are offered; women receive appropriate follow-up care and treatment. They also will work in co-ordination with the other staff members in the program.

Physicians, nurses, CHWs are the health care providers in this program, and they will be given comprehensive training as soon as they were recruited for the program.

7.5.1. Client assessment and preparation for screening

A basic assessment should be done (history taking) to all women before the screening test, and confidentiality assurance will be given. The provider will explain woman screening procedure will be done thus alleviate anxiety. (See **Appendix 5: Guidelines for history taking and Appendix 6: Guidelines for informed consent**)

7.6. Screening with *care* HPV Test

On the day of screening, the women will be informed that the trained nurse can collect the sample or women can do self –collection. If the woman wishes to do the specimen collection by the nurse, then the sample will be collected inserting a small brush or swab into the vagina and twist it around the area. If the woman is willing to do self-collection, the trained nurse will provide clear information about the procedure. Also, if the woman can read, the instruction manual will be given to her. If she is unable to read, then the nurse will provide education. There is a specific guideline for the self-collection of the sample (**see Appendix 6**). Self-collection of samples can be done in the facility; a private room will be allotted for this purpose.

The result will be obtained in 2-3 hours. If the result is negative, the woman will be advised to take a screening test after five years. If the test is positive, VIA will be used to determine the treatment method; eligible for cryotherapy or not; suspicious for cervical cancer or not. If the women identified as positive in the screening test, she has to be given thorough

counseling about the treatment options and its benefits. (See **Appendix 7: Guidelines for counseling women with positive screening results**)

7.7. Cryotherapy²⁰

The proposed program will use cryotherapy procedure as a treatment option. This method is relatively simple and inexpensive. It can be performed by health care providers at all levels (physicians, nurses, nursing midwives) and needs few days of training. No need surgical room and anesthesia; very fast; takes only 15 minutes; no need for electricity; in the context where the screen and treat approach is practiced, it is highly recommended as the treatment on the same day is highly possible. (See **Appendix 8: Guidelines of cryotherapy**)

Women who identified as positive in *care* HPV test will be given cryotherapy. Before giving the treatment, eligibility for cryotherapy should be determined by the VIA method. Cryotherapy can be given if the entire squamocolumnar junction of the cervix is visible and the lesion does not cover more than three-quarters of the cervix by VIA method. The woman is not eligible for cryotherapy if the lesion extends beyond the cryoprobe or extends into the endocervical canal. VIA also helps to reveal whether the cervix is suspicious for cancer or not. If suspicious for cancer, the woman is not eligible for cryotherapy. After the procedure, it takes one month for the regeneration of cervical tissue. The woman should be informed that she will have profuse watery discharge, and she should avoid sexual intercourse until the discharge stops otherwise use condom in case if the sexual intercourse is unavoidable

If not eligible for cryotherapy, Loop Electrosurgical Excision Procedure (LEEP) is the alternative option. However, LEEP needs at least minor surgical procedure room, and there is need of supervision of the gynecologist. Hence, the woman will be referred to relevant facilities

if she needs LEEP. In the case of cryotherapy, the woman will be advised to come for the follow-up at one year after the initial treatment. If the VIA result is suspicious for cervical cancer, an appropriate referral will be given by the provider for further diagnosis and treatment. (See **Appendix 9(a): flow chart of screen and treat approach and Appendix 9(b) guidelines for screen and treat approach**)

7.8. Referral system

The program will have an effective referral and system to make the diagnosis and treatment accessible for the women. The woman will be given the referral card to approach the clinic or hospital. The hospital will do the diagnostic tests or treatment (e.g. LEEP) as appropriate. After the procedure, they will resend the referral card to the Physician (team leader) mentioning the status of the woman. (See **Appendix 10: Sample referral letters for the diagnosis or treatment**). Depends on the economic status of the woman, she can either get the treatment in the private hospital or she can approach government hospital where the treatment is free of cost. If woman identified as suspicious for cancer, she will be referred to appropriate health care centers for further diagnosis and treatment.

7.9. Timeline

The proposed program will take five years to complete. It will start January 1, 2017, and end on December 31, 2022. First, three months will be dedicated to the planning phase. Tasks to be accomplished: Recruitment of human resource, hiring/identifying premises at the Talukas, identifying the target population for assessing needs, mapping and acquiring support from the local stakeholders, establishing effective referral system with the local health care facility, conducting need assessment, implementing a demonstration project in one of the selected.

Implementation will be delivered in two phases. The first phase will be finished by 25 months and the second phase will be completed in another 25 months. There will be one mid-term evaluation by the end of the first phase of implementation. Then there will be another evaluation carried out by the end of the second phase of implementation. After completing implementation, two months will be dedicated to final reporting the assessment to donor organization. (See **Table 4: Timeline chart**)

7.10. Potential barriers to implementation

The proposed program will be halt or delayed by many expected as well as unexpected circumstances. Hence the program team will consider the below-mentioned barriers and be cautious about them.

- Natural calamities such as heavy rain or flood may halt the program in certain areas
- Local religious festivals such as Diwali, Pongal (traditional festival of Tamil people), may intrude the progression
- Elections for Indian federal government (Parliament) that will be conducted in 2019 may halt the process
- Unexpected deaths in the villages may interrupt the educational sessions as well as screening campaigns
- State level **bandh** (general closure of all activities in the state) may delay the program implementation.

8. Evaluation

The aim of this of this program is to reduce the burden of cervical cancer among women of Coimbatore district. To achieve this goal, the program has three objectives. Out of these three, the first objective will be taken for the evaluation purpose. The evaluation will focus on the change in knowledge of women after the educational intervention. According to the first objective of the program, the proportion of women with good or satisfactory knowledge about cervical cancer and screening will increase to 20% in Coimbatore. The proposed evaluation will have the following stages.

- i. Setting evaluation questions and hypothesis
- ii. Deciding on evidence of program merit such as effectiveness
- iii. Design an evaluation
- iv. Selection of participants for the evaluation
- v. Collecting data
- vi. Managing data
- vii. Analysis of data
- viii. Reporting the results

8.1. Evaluation questions and hypothesis

i. Evaluation question

After an educational intervention (4 months later) on cervical cancer and its screening methods, will the proportion of women with satisfactory or good knowledge be increased to 20% in Coimbatore district compared to control group in Madurai district?

Null hypothesis

No difference exists between the knowledge of women about cervical cancer between the intervention and control groups four months after the educational program.

Alternative hypothesis

There will be a difference in knowledge of women about cervical cancer between the intervention and control groups four months after the educational program.

ii. Deciding on evidence of program merit such as effectiveness

Evidence suggests that the educational intervention increases the proportion women with satisfactory or good knowledge to more than 20%.⁵⁸ However, to be more realistic in the given social context (Coimbatore district), the proposed evaluation plan sets the minimum proportionate change of knowledge (20%).

iii. Evaluation design

For the evaluation purpose, quasi-experimental non-equivalent control group (pre and post- panel design) will be used. This design is usually used to evaluate interventions that do not

Exclusion criteria

- Women who already underwent screening test before (last 12 months) the intervention
- Women with health care educational background (e.g. nurse)

Sampling method

The proposed evaluation will use multi-stage cluster sampling method. The evaluation team will randomly choose ten villages from the first phase of program implementation (150 villages will be covered in the first phase). Ten villages from intervention and ten villages from control district are the clusters. After the random selection of clusters (villages), the evaluation team will obtain the voters list of those clusters from the election commission. Then they will select the eligible women based on their date of birth; e.g. if the woman were born between 1957 and 1987, her name would be chosen for the random sampling. After choosing all eligible name lists, the evaluation team will put numbers to the names. Then based on the simple random sampling method 13 women will be chosen from each village. This will be achieved by running the numbers (provided in the voter's list) in the computer using Micro Soft Office Excel software. The same method will be applied in to select the control group from Madurai district.

Advantages

- Easy to implement
- Cheap and time saving.
- Representativeness is high

Disadvantages

- This method can only be carried if the complete list of target age group women is available (e.g. voters list)
- If we have the full list, there is a possibility that the selected women may or may not attend the educational program or she may not be interested in participating in the survey.

Sampling unit

Sampling unit in this evaluation plan is woman aged between 30-59 years old and living in the two districts

Sample size calculation

The proposed evaluation will set the type I error (alpha) as 0.05 (5%) and the power (π) as 0.9 (90%). The sample size will be calculated based on proportion to size method. Formula of this method

$$n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1 - p_2)^2$$

- Where, $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05, and the critical value is 1.96)
- Z_{β} is the critical value of the normal distribution at β
- p_1 and p_2 are the expected sample proportions of the two groups. The proposed evaluation expects a 20 % percentage (percentage of women with satisfactory or good knowledge) increase in the intervention group (p_1); in the control group, it expects only 9 % (p_2).

The initial sample size needed for this evaluation is 428 (214 from intervention district and 214 from control district). According to this sample size the cluster size is 21 (from each cluster 21 women will be randomly selected). Taking into account a design effect of 1.2 (small cluster size), we can get a sample size of 514. Based on the literature, the proposed evaluation expects a 20% of attrition.⁶¹ Hence, an additional 64 women (20% of total sample) will be taken in the evaluation to address the attrition, and the final sample size will be 617 (control subjects 309 and intervention 309). The cluster size will be 31; from each village, the evaluation team will select 31 women randomly. The sample size is calculated using the STATA.13 software.

Sampling frame

The proposed evaluation will use voters' list as the sampling frame to identify intervention group as well as the control group. Voters' list is prepared by election commission of India. Every citizen in India, after completing 18 years of age will be eligible to cast their vote in the central (federal) election as well as in state assembly election. Every year, election commission of India update the list of eligible voters by household surveys and update it. Thus by obtaining this voter's list from the election commission at Talukas, the eligible women can be selected. Before implementing the program in the village, the evaluation team will obtain the

voter's list from election commission (located in Talukas). The state legislative assembly election (to select members of Tamil Nadu state legislative assembly) has been conducted in May 2016. Therefore, the proposed evaluation expects that the election commission will have the latest version of voter's list based on women's current citizenship and age. Thus the target group of women (30-59 years old) for the evaluation will be identified.

Variables

Based on the literature, socio-demographic information such as age, marital status, education, the number of children, and occupation are considered as independent variables.^{42,}
^{58,62} On the other hand, knowledge of cervical cancer (symptoms and risk factors) and screening methods are considered as dependent variables.^{42, 58,62}

Ethical considerations

The proposed evaluation will use oral informed consent from all the study participants before the pre-test. The study will be approved by the Institutional Review Board (IRB) of the American University of Armenia (AUA). In a case of any changes in the study in future (e.g. during implementation after finding funding), the study will be revised by the IRB, AUA for further approval. All the participants in the control group will be provided with educational materials that are distributed to the intervention group but only after the post-test. (See Appendix **11 (a): informed consent for intervention group and 11 (b): informed consent form for control group.**)

v. Data collection

All eligible women will be invited to the educational program. However, the questionnaire for the pre-test in the evaluation will be administered to women whose ID numbers were randomly chosen for the evaluation purpose. If the particular woman comes for the educational session and willing to participate in the pre-test, then the interviewer will conduct the survey (pre-test). If she does not attend the educational session or not willing to participate in the survey, then the next woman in the list will be contacted for the survey. This will be applied until we get the expected number of sample from each village. Those who have completed the pre-test will be contacted after four months for the post-test. The same method will be applied to identify the control group in Madurai district, but the only difference is that there will not be any intervention. Hence, the survey will be household, face-to-face interview. All the participants in the control group will be provided with the educational materials that have key messages about cervical cancer and prevention methods. The study setting for pre-test is different between both groups; this would lead to bias in the result. This will be considered as the limitation of the study.

The baseline survey will be conducted among the selected participants using the validated questionnaire that has two parts. The first part is adapted from cervical cancer awareness measurement (CCAM, UK)⁶² and the second part is adapted based on HBM. To assess the knowledge, only the first part will be analyzed. There are six domains in the first part of the questionnaire; (i) warning signs and symptoms of cervical cancer; (ii) cervical cancer and age; (iii) help-seeking behaviour; (iv) risk factors; (v) confidence on identifying the cervical cancer symptoms; (vi) available cervical cancer prevention program in the state. The baseline survey will take around 20-30 minutes to complete. The questionnaire also contains demographic

information such as age, marital status, and number of children, educational background, occupation and income status. Based on the literature if the respondents scored less than 38% they will be considered as having very poor knowledge; scoring from 38% to 49% will be assigned as poor knowledge; scoring from 50%-59% will be considered as satisfactory; scoring equal or higher than 60% will be considered as good.⁶¹ (See Appendix 12: *Instrument part I*).

In the second part, there are five domains that are based on constructs of HBM. The aim of these domains is to assess the changes in the behaviour of women to undergo screening test. But for this evaluation purpose, it will not be taken into analysis but in future, if the donor organization interested to know the screening behaviour of women in the intervention district then this part will be considered and analysed. (See Appendix 12: *Instrument part II*). Hence, both parts will be completed during the survey. The questionnaire will be translated into Tamil and will be piloted before the pre-test. The proposed evaluation will use only female interviewer to avoid the inconvenience to women in answering few sensitive questions. All the interviewers will be trained by the team leaders in the regional offices.

vi. Data management and analysis

After collecting the data, cross-checking will be conducted by the project leaders then it will be entered by the data entry personnel. Exploratory analysis will be conducted to clean the data by finding outliers, missing values, and distribution of variables. The analysis will include descriptive analysis, independent t-test for comparing the knowledge score of two groups and bivariate and multivariate linear regression analysis for assessing the relationship between independent and dependent variables. All the data will be analyzed by using SPSS, version 22.

Sampling report

Evaluation	Report
Evaluation question	After an educational intervention (4 months later) on cervical cancer and its screening methods, will the proportionate of women (30-59 years) with satisfactory or good knowledge increase from 7 to 20% in Coimbatore district when compared to the control group?
Evidence of effectiveness	Evidence suggests that the educational intervention to the target age group women will increase the proportion of knowledge of women to more than 20%. ⁵⁸
Evaluation design	Quasi-experimental study design with Non-equivalent control groups (pre-test and post-test)
Independent variable	<ul style="list-style-type: none"> • Socio- demographic status <ul style="list-style-type: none"> ➤ Age ➤ Marital status ➤ Number of children ➤ Education ➤ Occupation ➤ Income
Dependent variable	<ul style="list-style-type: none"> • Knowledge of warning signs and symptoms of cervical cancer • Knowledge of cervical cancer and age • Knowledge of health seeking behaviour • Knowledge of risk factors • Confidence in identifying the cervical cancer symptoms • Knowledge of screening available test in Tamil Nadu

Evaluation	Report
Inclusion criteria	<ul style="list-style-type: none"> • Women aged between 30-59 years old • Citizens (women) of Coimbatore district • Understand and speak in Tamil
Exclusion criteria	<ul style="list-style-type: none"> • Women already underwent screening test before (last 12 months) the intervention • Women with health care educational background (e.g. nurse)
Data source	Validated questionnaire (CCAM, UK)
Sampling method	Multi-stage cluster sampling
Sample size	617

Evaluation team

The CEO of the program will be the chief evaluator who will lead the evaluation process and report the result to donor organization. The project leaders with the MPH degree will be the secondary level evaluators who will be the responsible person to present the result to CEO. The team leaders will be the responsible ones for collecting data from field leaders and forward them from regional office to the head office. The field staff (e.g. trained medical social worker) will collect the data from the participants and submit them to the field leaders.

vii. Reporting the results

As it is already mentioned, there will be two evaluations (mid-term and final). The results of both evaluations will be delivered to the donor organization. The chief executive officer and the program leaders will be the responsible persons for this task.

Threats to internal validity

History: there might be a chance of occurrence of various events other than the intervention that would bias the result. This threat cannot be addressed and will be considered as the limitation of the study.

Testing: Since, the same questionnaire will be used both in the pre-test and post-test, respondents would remember the answers that may influence response. This threat cannot be addressed and will be considered as a limitation of the study.

Attrition: this cannot be a threat in this evaluation because the sample size is calculated by considering attrition (based on evidence) of 20%.

Instrumentation: in this evaluation, instrumentation will not be a threat because same questionnaire (without any changes) will be used both in pre-test as well as post-test.

Compensatory rivalry: this will be a threat to internal validity since the participants may aware that they are going to be assessed again for the post-test. But this cannot be minimized, and it will be considered as the limitation of the study.

Threats to external validity

Testing/intervention interaction: the change will be due to pre-test plus intervention (educational program) rather than the intervention alone. However, this issue will be addressed by having the comparison group from another district in which there will not be any intervention.

Selection intervention interaction: this will not be a threat to external validity because the selected participants will from all villages thus they represent the whole population.

Multiple intervention interferences: this could be a threat to external validity because there might be many programs exist in other settings. So the result from Coimbatore district cannot be generalizable to other settings.

9. Summary

The proposed program uses an evidence based approach ('screen and treat') that is recommended by WHO, to reduce the burden of cervical cancer in Coimbatore district of Tamil Nadu state, India. The program promotes the knowledge and screening behaviour of women by formal educational sessions. It uses the rapid HPV DNA test (*care* HPV) as the primary screening method. Consequently the program aims to identify the women who are at risk of developing cervical cancer and treat them on the day of screening. The program refers the women who are suspicious for cervical cancer to appropriate health care centres for diagnosis and treatment. It also provides a follow-up screening as per the recommendation by WHO. The impact of program will be assessed by evaluation plan and the final results will be delivered to the donor organization. Public health professionals, physicians, nurses, community health workers and women self-help group members are the key players of the program. Thus by

introducing the evidence based approach, the burden of cervical cancer in Coimbatore will be considerably lowered.

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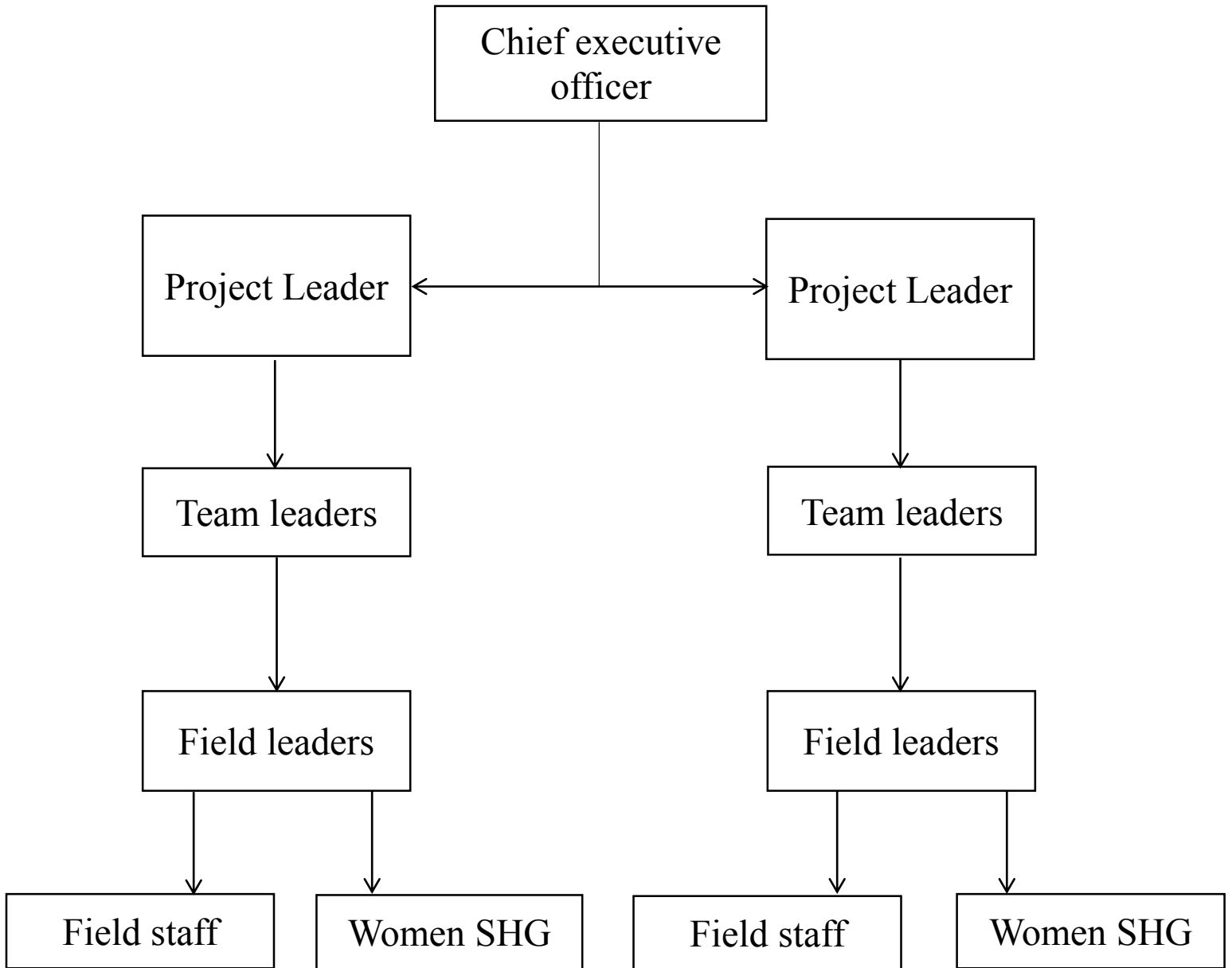
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Appendix 1: Organizational chart



Appendix: 2

Key messages for men

- Encourage the women at your home (mother, sister, and partner) to undergo screening if they are 30-59 years old
- Encourage women to take treatment if they are diagnosed with precancerous lesion
- Prevent all sexually transmitted diseases by using condoms

Basic information about cervical cancer for men

- Cervical cancer is a women's disease caused by infection with virus known as HPV.
- This infection will not show any symptoms until late years of life but few women will be affected by pre-cancer lesions
- If not diagnosed and treated earlier the pre-cancer lesion will be progressed to cervical cancer
- Since HPV infection easily spread through sexual contact, men can help to prevent it
- Rarely, some types of HPV causing cervical cancer can also cause cancer of mouth, anus, and penis
- Some types of HPV cannot cause cervical cancer but produce genital warts both in men and women

- Using condom can give some protection but not a complete protection against HPV infection since penetration is not the only way of spread of infection
- Smoking increases the development of cervical cancer among women who are infected by HPV
- You can support your partner to obtain care if she is diagnosed with pre-cancerous lesion or cervical cancer; accompanying her to clinic for treatment
- Woman needs both physical and emotional support if she is diagnosed and treated for pre-cancer and cervical cancer

(Source: comprehensive cervical cancer control: *A guide to essential practice*, WHO, 2014)

Appendix 3: Essential knowledge about cervical cancer

- What is cervical cancer?
- What is pre-cancer?
- How can we prevent cervical cancer?
- Who should be screened?
- Which preventive measures are available locally?
- Where and when can these services be accessed?

Five key messages about screening and treatment:

- Cervical cancer is a disease that can be prevented
- There are tests available to detect early changes of cervix (pre-cancerous lesions) that may be progressed to cervical cancer if left untreated
- There are treatment available for these early changes that are safe
- All women aged 30-59 years should be screened for cervical cancer at least once in their life time
- There is no need to die from cervical cancer

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 4: Guidelines for counseling

Counseling is usually personal and confidential communication with the aim to help women and sometimes-family members to make informed decisions. An effective counselor must have the ability to listen, as well as react to the questions arisen by the customers.

Counselor should be able to answer the following basic questions about cervical cancer

- What is cervix and where is it located? How can it be examined?
- What is cervical cancer?
- What is precancerous lesion? How does it differ from cervical cancer?
- How can cervical cancer be prevented? (Explain how screening test used to detect the precancerous lesions before it progress to cervical cancer)
- Who is likely to get cervical cancer and who should be screened?
 - Explain the women that cervical cancer develops during late 40s or 50s but the precancerous lesion can be found right from the 30s. Hence screening is done from 30 to 59 years old women
- How accurate is the screening test?
 - Inform them that no test is 100% accurate in determining the precancerous lesions. However the advanced test going to be done to them will be more easy, effective less expensive and less time consuming

- Why is it important to detect precancerous lesion by screening methods?
 - Explain the client that the detection of precancerous lesion will eventually lead to the treatment that are safe and easy; also we can prevent the development of cervical cancer

Responsibility of counselor

The counselor should make sure that:

- The client understands the information and the choices provided
- The conversation is confidential
- The communication is private
- Mutual trust is established between counselor and client

Suggested steps to provide counseling

- Welcome the client with a warm wish with name and introduce yourself
- Sit close enough to the client so that she feel comfort
- Assure her that the conversation will not be disclosed to anyone
- Use the mother tongue (Tamil) of the client so that she can understand easily
- Try to find out her real concerns
- Explain all the options available and discuss the procedure and merits of the procedures

- Make sure she understand the topic by let her repeat few core areas of the conversation
- Assist her to come to a decision by providing clear information
- Respect her decision and choice
- Invite her to return whenever she wishes and needs

Additional tips for good counseling

- Use a natural understand manner
- Place yourself in the client position
- Use appropriate body language
- Use visual aids if available
- Ask open-ended question in order to make the client to speak
- Motivate her to rise questions and answer them appropriately
- Allocate enough time for the session

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 5: Guidelines for history taking

The aim of collecting history is to assess whether the woman has any specific risk factors. Though it is difficult for the women to give an open answer to the sexually related issues, the provider can overcome this by using culturally appropriate language.

Information to be obtained from the client

- Age, education, number of pregnancies, births and living children, last menstrual period, menstrual pattern, previous and present contraception
- Previous cervical cancer screening tests (if done) and their dates and result
- Medical history
- Risk factors related to behavior of the woman; chewing/smoking tobacco
- Any signs and symptoms of cervical cancer and other illness

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 6: guidelines for informed consent

Before performing, the procedure sufficient information will be given to the woman and after getting acceptance and agreement from her the procedure will be done. The explanation will include description of procedure, time it takes, level of pain or discomfort, and possible complications post-test. In addition, meaning of positive result, treatment options, and possible consequence if she does not take the treatment. Hence, the woman will be able to decide where to take the test or not. If she agrees to take the test, verbal informed consent will be received.

Guidelines for informed consent

- Informed consent should be received before the procedure not after it
- Privacy should be maintained
- Be clear and direct; avoid using words that are difficult to understand (e.g. medical term; oncology)
- Provide ample of time for the client to understand the explanation. Use picture to illustrate the explanations. Encourage her to raise questions and clarify the doubts
- After all the queries and concerns have been addressed, ask the woman for the formal consent
- If woman shows willingness to add family members (e.g. life partner) we can do so in the decision making process

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 7: Guidelines for counseling women after positive screening test results

(i). Positive but not suspicious for cervical cancer

- Congratulate her for taking the screening test that helps to prevent cervical cancer
- Inform her that positive HPV test means that she has only early cell changes due to HPV infection but not the cervical cancer
- HPV infection could have been occurred during sexual intercourse
- HPV infection does not mean that the women will get promiscuity or infidelity
- Although condoms prevent most of the sexually transmitted infections, they do not completely protect from HPV infection
- There will not be any difficulties in getting pregnant if she receives treatment

(ii). Positive test result with suspicious for cervical cancer

- Explain the woman that there are cellular changes at cervix that need to be tested further to get complete diagnosis
- Do not tell her that she has cancer as cervical cancer will be diagnosed only after cervical biopsy
- Ask her that she is willing to involve any family members if present (on the day of test) in the discussion session about the treatment

- Explain her that there is a treatment available that will cure the cellular changes; this will be the primary focus at this point
- Provide information about the referral for further treatment and collect all contact details for future communication if necessary
- Ask her whether she has any difficulty in obtaining further care; unsupportiveness from the partner; financial barrier and lack of transport facility and also provide possible alternative solutions if available
- Fix a follow-up date to make sure she receives necessary care

Role of provider

- Setting up a system to track all referrals to make sure that the woman receives required care
- Ensure that the woman as well as her family members are aware of importance of going regularly for the fixed appointments
- Follow-up with the woman and her family to ensure that they understand the outcome of the further tests and treatment

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 8: Guidelines for cryotherapy

Cryotherapy is the application of highly cooled metallic disc into the cervix to freeze the abnormal tissues. This takes about 15 minutes to complete and causes mild cramping for few days and watery discharge up-to one month.

Inclusion criteria (all must be satisfied)

- Positive screening test result
- Lesion must be small enough that could be covered by cryopobe
- Lesions as well as all edges of the lesion must be visible and it should not be extended into to the endo-cervix and vaginal wall

Exclusion criteria (if any are satisfied)

- Suspicious for invasive disease or glandular dysplasia
- Lesion extends beyond the cryopobe edge
- Currently pregnant
- Active menstruation
- Pelvic inflammatory disease

Equipment and supplies for cryotherapy

- High level disinfectant speculum
- High level disinfectant, disposable gloves

- Cotton swabs for wiping the cervix
- Normal saline solution
- Cryosurgery unit along with adequate gas supply; carbon dioxide and nitrous oxide

Preparation

- Explain the procedure to the woman
- Make sure the woman has understood the procedure and provided informed consent
- Show the cryotherapy equipment and explain how it is going to be performed
- Prepare the patient for a gynecological examination and perform it through a speculum
- After ensuring that there is no infection, proceed the cryotherapy
- If there is an infection of cervix, refer her for appropriate treatment but fix an appointment before she leaves.

Procedure

- Wipe the cervix by the cotton swab that has been soaked in saline and wait for few minutes
- Apply acetic acid to have the outline of abnormal tissue and wait for further few minutes until the white area appears
 - If white area covers more than three quarters of the cervix or extend into the endo-cervical canal, they are not eligible for the cryotherapy

- Remove the speculum and after the woman dressed, tell her that cryotherapy is not suitable for her; also mention that there is another option, LEEP
- After explaining the procedure (LEEP), assist her to get an appointment in a secondary level hospital
- If the acetic acid examination satisfy the requirements for cryotherapy then start the procedure
- Tell the woman that she might be having mild cramping or discomfort during the process
- Wipe the cryoprobe surface by saline to get optimal effectiveness
- Apply the tip onto the mouth of the cervix and make sure the probe adequately covers the lesion. If it does not cover the lesion completely, then remove the probe and refer the woman to LEEP
- Before freezing, make sure that the vagina is not in contact with the cryoprobe otherwise it may freeze the vaginal wall.
- Set the timer and release the gas trigger to cool the probe
- Formation of ice can be observed over the tip of the cryoprobe and on the target area of cervix
- Once the frozen area extends 4-5 mm beyond the edge of the cryoprobe, we can consider that the freezing is enough
- Totally there should be two cycles of freezing and melting

- Three minutes of freezing, followed by five minutes of melting, followed by another three minutes of freezing
- Once the second freezing has been done, provide some time for thawing before taking out the probe; cervical tissues may be pulled off, if the probe is taken before adequate thawing
- Give a gentle rotation of the probe then take it out. The frozen area will become white.
- Carefully examine the cervix for bleeding; if bleeding occurs, apply Monsel's paste.
- Remove the speculum

After the procedure

- Provide a sanitary pad to the women
- To avoid infection instruct her to avoid sexual intercourse as well as vaginal tampons for up-to four weeks until the discharge stops
- Provide her with a condom and instruct her to use it in case of unavoidable sexual intercourse
- Provide information about possible complications and advise her to visit the clinic immediately if the following symptoms arise
 - Fever with more than 38 degree Celsius or shaking chills
 - Severe lower abdominal pain
 - Foul-smelling or pus-like discharge
 - Bleeding for more than two days and bleeding with clots

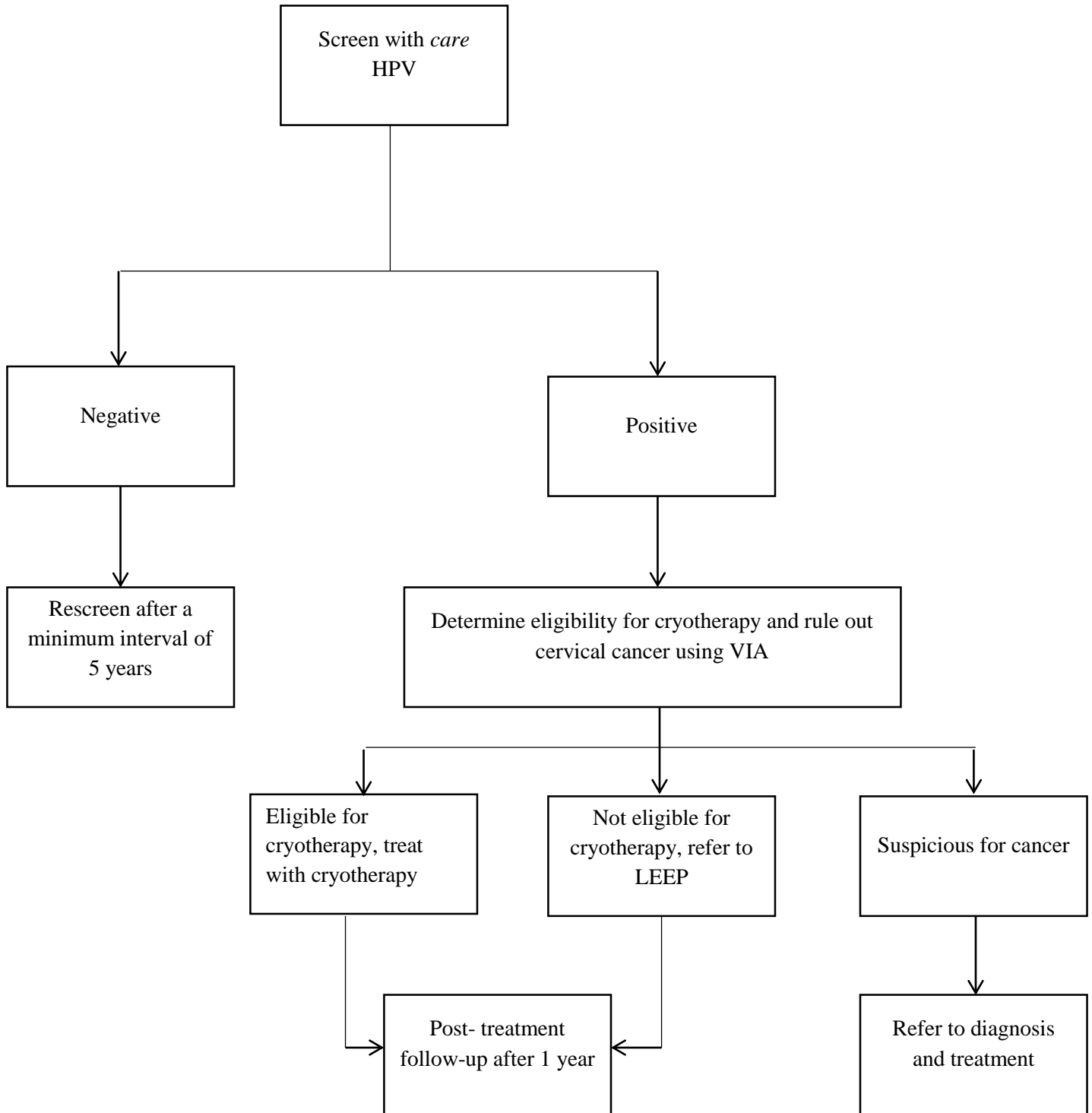
- Advise her to return after 12 months for a repeat cervical screening test

Processing the used equipment

- Decontaminate cryotherapy unit, hose and the regulator by alcohol
- Wash the cryo tip and the plastic sleeve with soap water until visibly clean. Rinse these two with clean water
- High level disinfection of cryotip can be done by one of the below mentioned methods
 - Boil in water for 20 minutes or
 - Steam for 20 minutes
 - Soak in chemical disinfectant (0.1% chlorine solution or 2-4% glutaral) for 20 minutes and then rinse with boiled water
- Make sure that the hollow part of the cryotip is completely dry when used for next time otherwise, the stagnant water will freeze in this area and cracked by the probe thus treatment may not work
- Use a rubber cap over the hollow area or dry it completely after the disinfectant process
- If the above-mentioned disinfectant method is not available, the cryotip as well as sleeve can be disinfected by soaking in 70-90% ethanol or isopropanol for 20 minutes. Allow drying by air and reassemble them.

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 9(a): flow-chart for screen and treat approach



(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 9(b) guidelines for screen and treat approach

Screen with care HPV test and treat with cryotherapy. If test is positive, VIA will be used to determine eligibility for cryotherapy

Taking a sample for HPV testing

- The provider can collect the sample by inserting a long swab to the top of the vagina, twisting it around the area and place it in the appropriate solution.
- This can be done also by the woman herself but a clear demonstration should be given along with the swab and a solution container.
- Self-collection will be done at the facility if available or at home

After taking sample

- Label the container with the client's name, center code number or village code number
- Do the process as per the instruction given by the manufacturer
- When giving the test result (2.5-3 hours later on the same day), explain the woman what does the result mean
- If the test result is negative suggest the client to take the test after 5 years
- If the test result is positive, do VIA to determine whether the woman is eligible for cryotherapy and also to rule out cervical cancer

- If suspicious for cervical cancer, refer the client to further diagnosis and treatment
- If not eligible for cryotherapy, suggest her to undergo LEEP
- Suggest the client to come for follow-up after one year

(Source: comprehensive cervical cancer control: *A guide to essential practice*, WHO, 2014)

**Appendix 10 (a): sample card that can be used as a part of a system to track patients who
need a repeat screening test**

Cervical screening tracking card: Patient recall for screening test

Name: _____

Patient Number: _____ **Date of birth:** _____

Home address: _____

Work address: _____

Telephone number: _____

Date screening done: _____

Screening result: _____

Date when client was asked to return: _____

Follow-up:

Date of repeat screening test:

Action taken if she did not return: _____ **Note sent (date):** _____

Notes:

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 10 (b): Sample referral card that can be used as part of system to track patients referred for further diagnostic evaluation

Cervical screening

tracking card: Patient referral

Name: _____

Patient number: _____ **Date of birth** _____

Home address: _____

Work address: _____

Telephone number: _____

Date of screening test done: _____

Screening test result: _____

Appointment for referral at: _____ (name of the referral site)

Date of referral appointment: _____

Tracking record:

Date patient informed of referral appointment: _____

Outcome of referral: _____

(Source: comprehensive cervical cancer control: *A guide to essential practice*, WHO, 2014)

**Appendix 10 (c): Sample referral letter that can be used to inform the referring clinic
about the outcome of patient's diagnostic or treatment evaluation**

To : _____ (name of the referring hospital)

Name of the patient: _____ **Patient number:** _____

From: _____ (name of the referral site)

Patient was seen in our hospital on (date): _____

Diagnostic test of _____ **were performed on (date)** _____

Final diagnosis: _____

Management provided: _____

Recommended follow-up: _____

Thank you for your referral. Please contact us should you need further information

Yours sincerely,

Name

Signature

Date

(Source: comprehensive cervical cancer control: A guide to essential practice, WHO, 2014)

Appendix 11 (a): informed consent for intervention group

American University of Armenia

Institutional Review Board

Care HPV; an alternative screening test for Cervical Cancer Prevention in Coimbatore district of
Tamil Nadu state, India.

Consent form (English)

Hello! I am _____, working for the Care Coimbatore project. The aim of this project is to reduce the burden of cervical cancer in Coimbatore district. You have been approached as one of the participants in this survey since you are living in Coimbatore district, your age falls between 30-59 years, and you speak Tamil. Your participation is voluntary and if you are willing to participate, I will ask few questions about cervical cancer and its screening methods.

You can attend the educational session even if you do not participate in the survey. After the educational session, you will be invited for the screening campaigns and if needed, you will be offered free treatment. Four months later, you will be contacted again to complete another survey.

The total duration of the interview will be 30 minutes. You can skip any question if you feel discomfort or not willing to answer and you can stop the interview at any time. The information you provide for this survey will be confidential and only the summary of information from all participants will be presented in the final report. By participating in this survey, there will not be any risk to you and the information provided by you will be very helpful for science and healthcare.

If you have more doubts about the survey, you can contact the principle investigator of the study, Dr. Amy Sandridge at the American University of Armenia (AUA), School of Public Health (+ 374 60 61 25 70). If you feel you have not been treated fairly or think you have been hurt by participating in this survey, please contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (+3754 60 612-561).

Do you agree to participate? Thank you. If yes, shall we continue?

Appendix 11 (b): informed consent for control group

American University of Armenia
Institutional Review Board
Cervical cancer knowledge survey
Consent form for control group (English)

Hello! I am _____, working for one of the cancer prevention project. The aim of this project is to reduce the burden of cervical cancer and to increase the knowledge of cervical cancer among women. You have been approached as one of the participants in this survey since you are living in Madurai district, your age falls between 30-59 years, and you speak Tamil. Your participation is voluntary and if you are willing to participate, I will ask few questions about cervical cancer and its screening methods.

The total duration of the interview will be 30 minutes. You can skip any question if you feel discomfort or not willing to answer and you can stop the interview at any time. Four months later, you will be contacted to complete another survey. The information you provide for this survey will be confidential and only the summary of information from all participants will be presented in the final report. By participating in this survey, there will not be any risk to you and the information provided by you will be very helpful for science and healthcare. In addition, after the second survey, you will be provided with educational materials that will be helpful to improve your knowledge about cervical cancer.

If you have more doubts about the survey, you can contact the principle investigator of the study, Dr. Amy Sandridge at the American University of Armenia (AUA), School of Public Health (+ 374 60 61 25 70). If you feel you have not been treated fairly or think you have been hurt by participating in this survey, please contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (+3754 60 612-561).

Do you agree to participate? Thank you. If yes, shall we continue?

Appendix 12

**Cervical Cancer Awareness Measurement (CCAM) and screening behaviour
assessment**

Interviewer ID

Interviewee ID

Date of the interview ___/___/___ **Day/Month/Year**

Start time ___:___

End time ___:___

Demographic information

1. Which city or village do you live in?

1. Urban/ City

2. Rural/village

3. Refusal

2. How old are you?

1. Don't know

2. Refused

3. Are you married?

- 1. Married
- 2. Divorced
- 3. Widowed
- 4. Never married
- 5. Refusal

4. How many years have been married?

- 1. Don't remember
- 2. Refusal

5. Have you ever been pregnant?

- 1. Yes

1. a. Number of births _____

1. b. Number of abortions (if any) _____

- 2. No
- 3. Refusal

Educational background

6. What is the highest level of education you have completed?

1. None
2. Primary school (1-5th standard)
3. Middle school (6-8th standard)
4. High school (9-10th standard)
5. Higher secondary school (11-12th standard)
6. College (Under graduate)
7. College (Post-graduation)

7. Can you read well in Tamil?

1. Yes
2. No

Occupation and Income

8. Do you work?

1. Yes
2. No

9. What do you work?

1. _____
2. Refusal

10. How many years have you been working or worked?

1. _____

2. Don't know

11. How many of you live in your house and approximately how much is the family income per year?

1. _____

2. Don't know

12. How much do you earn each month?

1. _____

2. Don't know

Part I: Knowledge of cervical cancer and symptoms

Domain 1: Warning signs

The following questions are all about cervical cancer, which is the cancer of neck of the womb (cervix)

1. There are many warning signs and symptoms of cervical cancer. Please name as many as you think of

Note: (Interviewer: prompt with 'anything else' until the woman cannot think of anything else. If the participant says, do not know any, prompt with 'are you sure?' and if necessary 'take a minute to think about it'. Write down all of the warning signs or symptoms that the participant mentions exactly as they say it.)

.....

.....

.....

3. Nothing

4. Do not know

99. Refusal

(The responses will be recorded on the blank space and the next question should not be shown to the respondent since it has the specific answers for the first question).

2. The following may or may not be warning signs for cervical cancer. We are interested in your opinion.

(Note for Interviewer: Do not prompt. If the respondent asks for the clarification about certain items within this of questions, please refer to the clarifications below. Please only read these if necessary)

- ‘Persistent’ in reference to any of the warning signs refers to 3 weeks or longer
- Do you think vaginal bleeding after the menopause could be a sign of cervical cancer? [POINT OF CLARIFICATION]: The menopause is when periods permanently stop.
- Do you think persistent pelvic pain could be a sign of cervical cancer? [POINT OF CLARIFICATION]: the pelvic area is between the hips and at the bottom of the spine

No	Question	Yes	No	Don't know
i.	Do you think vaginal bleeding between periods could be a sign of cervical cancer?			
ii.	Do you think persistent lower back pain could be a sign of cervical cancer?			
iii.	Do you think a persistent vaginal discharge that smells unpleasant could be a sign of cervical cancer?			
iv.	Do you think discomfort or pain during sex could be sign of cervical cancer?			
v.	Do you think menstrual periods that are heavier or longer than usual could be a sign of cervical cancer?			
vi.	Do you think persistent diarrhea could be a sign of cervical cancer?			

No	Question	Yes	No	Don't know
vii	Do you think vaginal bleeding after the menopause could be a sign of cervical cancer?			
viii	Do you think persistent pelvic pain could be a sign of cervical cancer?			
ix	Do you think vaginal bleeding during and after sex could be a sign of cervical cancer?			
x	Do you think blood in the stool or urine could be a sign of cervical cancer?			
xi	Do you think unexpected weight loss could be a sign of cervical cancer?			

Domain 2: Seeking help

3. If you had, a symptom that you thought might be a sign of cervical cancer how soon would, you contact your doctor to make an appointment to discuss it?

(Record the response)

Domain 3: Cervical cancer and age

4. **In the next year, who is most likely to develop cervical cancer in Tamil Nadu?**

a). women aged 20-29 years	<input type="checkbox"/>
b). women aged 30-59 years	<input type="checkbox"/>
c). women aged 60-69 years	<input type="checkbox"/>
d). women aged 70 or over	<input type="checkbox"/>
e). cervical cancer is unrelated to age	<input type="checkbox"/>

Domain 4: Risk factors

5. What things do you think affect a woman's chances of developing cervical cancer?

(Note for interviewer: Prompt with 'anything else?' until the respondent cannot think of any more signs. If the person says they do not know any, prompt with 'are you sure?' and if necessary 'take a minute to think about it'. Write down all of the risk factors that the person mentions exactly as they say it.)

.....

.....

.....

6. Nothing

7. Don't know

99. Refusal

(The responses will be recorded on the blank space and the next question should not be shown to the respondent since it has the specific answers for this question).

6. The following may or may not increase a woman's chance of developing cervical cancer. How much do you agree that each of these can increase a woman's chance of developing cervical cancer?

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
i.	Infection with HPV (human papilloma virus)					
ii.	Smoking/chewing any forms of tobacco					
iii.	Having a weakened immune system (e.g. because of immunosuppressant drugs, having a transplant or HIV/AIDS)					
iv.	Long term use of contraceptives					
v.	Infection with chlamydia (a sexually transmitted disease)					
vi.	Having a sexual partner who is not circumcised					
vii.	Starting to have sex at young age (before 17)					

viii.	Having many sexual partner					
No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
ix.	Having a sexual partner who has many sexual partners					
x.	Not going for regular screening test (e.g. Pap test)					

Domain 5: Confidence

7. How confident are you that you would notice a cervical cancer symptom?				
Not at all confident	Not very confident	Fairly confident	Very confident	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Domain6: Availability of screening services

		Yes	No	Don't know
8.a)	As far as you are aware, is there any state level program available to prevent cervical cancer in Tamil Nadu?			

8.b)	If yes, at what age women are invited for the cervical cancer screening tests in Tamil Nadu?_____	
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II. Attitude and Behavior Questionnaire based on Health Belief Model

Domain 1: Perceived Susceptibility

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
1	I think I am at risk for getting cervical cancer					
2	I am more likely than the average women to get cervical cancer are.					

Domain 2: Perceived Severity

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
3	Cervical cancer would threaten my relationship with my life partner.					
4	Most women who develop cervical cancer will die from it					
5	My whole life would change if I had cervical chance					

Domain 3: Perceived Benefits

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
6	When I get a cervical cancer screening test, I don't worry as much about cervical cancer					
7	Getting the screening test is the best way to detect cervical cancer					
8	Screening tests can detect cervical cancer in its early stages, when it is easier to cure					
9	Getting a screening test every year is an important thing for me to do in order to stay as healthy as I can					
10	Having a screening test every year will decrease my chances of dying from cervical cancer.					

Domain 4: Perceived Barriers

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
11	I do not understand what will be done during a screening test					
12	If I am destined to get cervical cancer, having a screening test will not prevent me from getting cervical cancer					
13	My partner is uncomfortable with me being examined by a male doctor					
14	Having a screening test is embarrassing for me					
15	My doctor is not available at times that are convenient for me to have a screening test					
16	I am uncomfortable with having a stranger perform a screening test.					
17	I do not know where to go or who to ask to get a screening test					

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
18	I do not need to get a screening test if I feel OK.					
19	Having a screening test will be painful and unpleasant.					
20	Having a screening test will take too much time					
21	Having a screening test would cost too much money.					
22	I have no means of transportation to the health clinic for a screening test.					
23	I am scared to have a screening test because I might learn that I have cancer.					

Domain 5: Self-efficacy

No	Question	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
24	I feel capable of arranging to have a screening test.					
25	I feel capable of getting a screening test.					
26	I feel capable of managing any emotional distress caused by screening test					

Thank you for taking time to answer my questions.

Now that the interview is over, would you like to ask any questions? Or do you have any comments?

Table 1 (a): The budget

Location	Personnel	Numbers	Items	Budget in USD for five years
Project heads office	Project Leaders	02	<ul style="list-style-type: none"> ➤ Salary ➤ Windows 8 PC x 2 ➤ Vehicle x 2 	<p>210000</p> <p>2000</p> <p>15000</p>
	Date Entry personnel	3	<ul style="list-style-type: none"> ➤ Salary ➤ Windows 8 PC x 3 	<p>36000</p> <p>10000</p>
	Secretary	3	<ul style="list-style-type: none"> ➤ Salary ➤ Windows 8 PC x 2 	<p>22000</p> <p>600</p>
	Accountant	3	<ul style="list-style-type: none"> ➤ Salary ➤ Windows 8 PC x 3 	<p>46000</p> <p>900</p>
Regional offices	Team leaders	10	<ul style="list-style-type: none"> ➤ Salary per campaign (for 10 members) ➤ Office (individual offices in each Talukas will be rented) ➤ Windows 8 PC x 10 	<p>180000</p> <p>44000</p> <p>10000</p> <p>3000</p>
	Field leaders	10	<ul style="list-style-type: none"> ➤ Salary (for 10 members) ➤ Portable laptop x 10 ➤ Travel allowance to the sites per campaign 	<p>9000</p> <p>2000</p> <p>10000</p>
	Data entry staff	4	<ul style="list-style-type: none"> ➤ Salary ➤ Windows 8 PC x 4 	<p>15000</p> <p>1200</p>
	Field staff	30	<ul style="list-style-type: none"> ➤ Salary per campaign ➤ Travel allowance 	<p>45000</p> <p>9000</p>
	SHG members	90	<ul style="list-style-type: none"> ➤ Salary per campaign ➤ Travel allowance 	<p>23000</p> <p>5000</p>
	Total			

Table 1 (b): Budget for supplies

Item	Cost per person (US\$)	Price
<i>care HPV</i>	5	2000000
VIA	5	1000000
Cryotherapy	45	4500000
Total	55	7500000

Table 2: project team and their duties and responsibilities

Personnel	Qualification	No	Responsibility
Chief executive officer	➤ Public Health Professional with MPH degree and 5 years of experience	01	<ul style="list-style-type: none"> ➤ Primary responsible person for mobilizing the fund and maintain close co-ordination with the funding organization ➤ Recruit project leaders ➤ Leader of planning, implementation and evaluation of the program in co-ordination with the project leaders ➤ Establish rapport with the local leaders such as politicians, health care providers, NGOs, higher level government administrators ➤ Chief evaluator of the program ➤ Conduct regular meeting with the project leaders, team leaders <ul style="list-style-type: none"> ✓ Discuss the progress ✓ Get feedback from them ✓ Provide feedback ✓ Make sure fund is adequate and used in an appropriate way ✓ Discuss the challenges and find new ways to solve the problems in co-ordination with colleagues ✓ Make sure the time line is keeping up ➤ Regular visits to the office of project leaders, team leaders, and make sure everything is progressing ➤ Periodic visits to the field to assess the process

			<ul style="list-style-type: none"> ➤ Report the evaluation result to donor organization
Project leader	<ul style="list-style-type: none"> ➤ Public Health professional (MPH) with minimum two 2 years of experience 	02	<ul style="list-style-type: none"> ➤ Secondary responsible person for planning, implementation and evaluation of the program in co-ordination with the CEO and project leaders ➤ Each person responsible for the implementation of program in five Talukas ➤ Each person is responsible to do lead the evaluation in their assigned villages ➤ Recruit team leaders ➤ Conduct situational and need analysis along with team leaders ➤ Meeting with team leaders ➤ Training of trainers (TOT): Design an evidence based educational materials, training strategies, workshops and deliver that to team leaders ➤ Report to the CEO about the progress of program ➤ Periodic field visit ➤ Report the results of evaluation to the CEO
	<ul style="list-style-type: none"> ➤ Gynaecological Oncologist with 2 years' experience 	02	<ul style="list-style-type: none"> ➤ Each person is responsible for 5 selected Talukas for the implantation of the program ➤ Planning the screening strategy <ul style="list-style-type: none"> ✓ Assess the medical equipment need and collaborate with the manufacturer ✓ Provide quotation for the equipment needed ✓ Periodic discussion with the project leaders and CEO ✓ Recruit team leaders based on the qualification

			<ul style="list-style-type: none"> ✓ Provide suggestions for the other project leaders for the designing a quality educational training programs ➤ Conduct periodic training sessions to the team leaders ✓ Demonstration of counselling methods to the team leaders ✓ Workshop on care HPV screening method and collection of specimens ✓ Demonstration of Cryotherapy treatment method ✓ Periodic training the team leaders about how to train the field staff providing counselling, screening, treatment and reference ➤ Design an effective referral system and collaborate with existing facilities; cancer centres, gynaecological centres ➤ Guide the team leaders in complicated situations in co-operation with the CEO and other project leaders ➤ Periodic visits to the screening sites on the day of scheduled screening ➤ Periodic report to the CEO about the progress
Team leaders	<ul style="list-style-type: none"> ➤ Gynaecologist with 2 years of community based clinical experience ➤ There will be two groups of team leaders each consist of 5 gynaecologist 	10	<ul style="list-style-type: none"> ➤ Undergo workshops and training programs conducted by project leaders ➤ Recruit field staff based on qualification ➤ Establish a good collaboration with the locally available women health centres to have a referral system ➤ Conduct training sessions to field staffs about

			<ul style="list-style-type: none"> ✓ Identifying target village and population ✓ Data collection ✓ Educational programs ✓ Screening procedure with care HPV ✓ Cryotherapy procedure ✓ Identifying the complicated or suspicious women during screening ✓ Counselling the women ✓ Process of effective referral <ul style="list-style-type: none"> ➤ Schedule and conduct screening campaigns in the villages based on the suggestions from the field workers ➤ Periodic field visits in their allocated Talukas ➤ Guiding the field staff during challenging situation ➤ Report to the project leaders about the progress
Field Leaders	➤ Community nurse with 5 years of experience	10	<ul style="list-style-type: none"> ➤ Lead the field staff ➤ Assessing the local needs ➤ Setting appropriate time for the educational and screening campaigns ➤ Fixing the issues arise on field ➤ Providing suggestions for the changes needed in educational and screening campaigns ➤ Supervise the data collection process for evaluation

Field staff	<p>➤ Community health worker (Medical social worker (male/female), nurse with ANM degree (female), women volunteers with an undergraduate degree) with two years of field experience</p>	30	<p>➤ Outreach and community mobilization</p> <ul style="list-style-type: none"> ✓ Identify the target women with by using of voters list and local leaders ✓ Reach the target village, communicate with the local leaders, and get support ✓ Recruit 3 members from women SHG based on their interest ✓ Train them with the educational materials and screening tests. ✓ Conduct education campaigns at villages ✓ Street plays, house-visits ✓ Conduct baseline data collection ✓ Establish and maintain relationship with local administrators for the successful campaigns ✓ Set a suitable day, time, and place for the screening campaign ✓ Get support from the team leaders whenever needed ✓ Educate women about the procedure self-collection of samples and whom to hand over the specimen ✓ Make sure that self-collected samples are received and transferred to the appropriate personnel in time ✓ Send the collected self-sample to the team leaders ✓ Forward the collected data to team leaders
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	<p>➤ Members from women self-help group</p>	90	<p>➤ Major players in community based educational</p> <ul style="list-style-type: none"> ✓ Attend training sessions conducted by the CHWs ✓ Assist the CHW to accomplish their job ✓ Establish relationship with other members of SHG to promote the educational campaigns ✓ Educate the target woman to collect the samples on her own, collect them by home visit and hand over them CHWs ✓ Home visits for baseline data collection, individual counselling, motivating women to participate in the screening campaign ✓ Assure them for the appropriate treatment and further referral if needed ✓ Ensure them with the confidentiality ✓ Clear their doubts (if know) otherwise direct them to CHW ✓ Help CHWs to find and set suitable time for the screening campaign ✓ Arrange the setting for screening campaigns that would be easy to access, and safe ✓ Follow-up visits to women who have been screened positive to make sure that they received cryotherapy and take the test after a month ✓ Report to the CHWs about the progress
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Data entry staff	➤ Data entry manager with Master degree in computer sciences and 5 years of experience in data entry	01	<ul style="list-style-type: none"> ➤ Collect data from both project leaders' office ➤ Check for the mistake by random check ups ➤ Communicate with the next level data entry staff for clarification ➤ Periodically communicate with the project leaders and CEO for the progress
	➤ Data entry staff at project leaders' office with 3 years of experience	02	<ul style="list-style-type: none"> ➤ Each will be assigned to receive data from 148 villages ➤ Collect the data from team leaders' office ➤ Do data management ➤ Periodically communicate with the project leaders and chief data entry personnel for any clarification
	➤ Data entry staff at team leaders' office with 2 years of experience	04	<ul style="list-style-type: none"> ➤ Each will be responsible to receive data that are collected by the field staff from 74 villages ➤ The team leaders will assign them with the particular villages ➤ Careful entry of data received ➤ If the data has missing or uncertain information, clarify them with the field staff ➤ Random check-up of the entered data ➤ Forward the data set to team leaders and make sure that it has been further forwarded to higher level data entry ➤ Cope-up with the higher level data entry staff if they need help ➤ Report to the team leaders about the progress

Administrative accountant	<ul style="list-style-type: none"> ➤ Chief accountant having master degree in finance management with 5 years of experience 	01	<ul style="list-style-type: none"> ➤ Primary responsible person of allocating the funding according to the plan given by the higher level managers; CEO and project leaders ➤ Establish collaboration with the local and international manufacturer for the purchase of equipment ➤ Revising the financial request given by the team leaders and make proper decision according to the suggestion by CEO ➤ Ensure that the adequate fund is released to base on the needs and periodic visits to the team leaders office, and field to assess the financial spending ➤ Make sure that the remuneration to all levels of staff is done on time ➤ Report to the CEO regularly about the progress
	<ul style="list-style-type: none"> ➤ Junior accountant at project leaders' office having master degree in finance management with 3 years of experience 	02	<ul style="list-style-type: none"> ➤ Each will be given responsibility for 148 villages and work in co-ordination with project leaders ➤ Assist chief accountant for allocating the fund to the team leaders' office ➤ Ensure that the money released is spent according to the needs ➤ Make sure the remuneration to all levels of staff is done on time ➤ Visit the field offices regularly to assess the appropriate use of the money

Secretary	<ul style="list-style-type: none"> ➤ Chief secretary at head office having basic degree in communication or relevant field 	01	<ul style="list-style-type: none"> ➤ Assist the CEO and project leaders with various task accomplishments such as documentation, meeting arrangements, responding to the enquiries, keeping up the schedules, diverting the office logistics. ➤ Receive the requests from other offices and forwarding them to CEO for further processing ➤ Communicate with all levels of leaders to set time for the meetings
	<ul style="list-style-type: none"> ➤ Regional secretary at team leaders' office having basic degree in communication and administration with 2 years of experience 	02	<ul style="list-style-type: none"> ➤ Assist the team leaders in the administration desktop work ➤ Assist team leaders in scheduling and arranging meetings ➤ Convey key information to the field staff as well as project leaders ➤ Divert the office logistics to the field staff and forward their requirements to the team leaders ➤ Respond to the queries and cope up with the timeline ➤ Make sure the timeline is followed

Table 3: Constructs of HBM ⁵⁶

Construct	Definition	Application
Perceived susceptibility	Belief about the chances of experiencing a risk or getting a condition or disease	Define population(s) at risk, and risk levels Personalize risk based on a person's characteristics or behaviour.
Perceived severity	Belief about how serious a condition and its sequel.	Specify consequences of risks.
Perceived benefits	Belief in efficacy of the advised action to reduce risk or seriousness of impact	Define action to take; how where, when. Clarify the positive effects to be expected.
Perceived barriers	Belief about the tangible and psychological costs of the advised action	Identify and reduce perceived barriers through reassurance, correction of misinformation, incentives, and assistance.
Cues to action	Strategies to activate "readiness"	Provide how-to information, promote awareness, use appropriate reminder systems.
Self- efficacy	Confidence in one's ability to take action	Provide training and guidance in performing recommended action. Use progressive goal setting Give verbal reinforcement. Demonstrate desired behaviours. Reduce anxiety.

Table 4: Time line

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
2017	Planning			Implementation phase I								
2018	Implementation phase I											
2019					Evaluation I	Planning		Implementation phase II				
	Implementation phase I											
2020	Implementation phase II											
2021	Implementation phase II								Evaluation II	Final reporting		